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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

**Reference: [Docket No. 00D-1542] "FDA Draft Guidance for Industry 21 CFR Part11;
Electronic Records; Electronic Signatures; Timestamps"**

Dear Sir or Madam:

Merck & Co., Inc. is a leading worldwide human health product company with a corporate strategy to discover new medicines through breakthrough research. Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many important pharmaceutical and biological products on the market today.

In fulfilling this strategy, Merck's operations use computer systems subject to this regulation, and as such Merck is interested in commenting on the FDA Draft Guidance for Industry 21 CFR Part11; Electronic Records; Electronic Signatures; Timestamps. This guidance is consistent with past guidance documents and Merck has one comment.

Systems Clock Security

The Systems Clock Security, described in Section 5.2, indicates that personnel should periodically conduct unannounced checks of computer clocks. Merck would recommend the language be changed to "should be periodically audited", but not necessarily unannounced.

We appreciate the FDA's effort to provide guidance on 21 CFR Part 11, and look forward to additional opportunities to comment on new guidance documents on this topic.

Sincerely,

00D-1542

A handwritten signature in black ink that reads "M. C. Elia".

C7

Michael C. Elia, Ph.D., DABT
Sr. Director
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